



# Proteomics International

LABORATORIES LTD

ASX Release  
27 April 2023

ASX code: PIQ

## Quarterly Activities Report

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a medical technology company at the forefront of precision medicine and predictive diagnostics, is pleased to provide the following update on its business activities for the three months to 31 March 2023 and subsequent to the period end.

- **Novel blood test for endometriosis presented at international conference:** Potential world-first blood test to improve screening for a disease that affects 1 in 9 women
- **Major milestones achieved as CPT PLA reimbursement code approved and becomes effective for PromarkerD in the United States:** Code is key to PromarkerD being covered by both Medicare and private health insurers in the US
- **US licensing negotiation in closing stages:** Proteomics International finalising terms with Sonic Healthcare USA to bring PromarkerD to the United States
- **Clinical Advisory Board expanded to support PromarkerD USA and global rollout:** New members comprise highly respected healthcare professionals and key opinion leaders (KOLs) specialising in primary care diabetes education and management
- **Distribution agreement for PromarkerD in Britain extended:** Deal with medical diagnostics company Apacor Limited extended for a further five years
- **Application for PromarkerD listing on Australian Medicare Benefits Schedule (MBS) to be resubmitted:** review committee notes potential wide uptake of the test and long term savings to the health system
- **Exercise of options:** The Company's balance sheet was boosted significantly following the exercise of options raising \$3.1 million before costs.

### OPERATIONAL HIGHLIGHTS

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Proteomics International's activities fall into three key areas:

- (i) commercialisation of PromarkerD, the predictive test for diabetic kidney disease (DKD)
- (ii) R&D for new diagnostic tests using the Promarker™ pipeline
- (iii) analytical services on a commercial basis

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## **i) Commercialisation of PromarkerD**

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### **CPT PLA reimbursement code approved and becomes effective in the United States**

[ASX: 3 January, 26 April] Proteomics International achieved a major milestone in the commercialisation of PromarkerD with the approval of a new dedicated CPT® Proprietary Laboratory Analyses (PLA) code for the test in the United States. The CPT PLA code—issued by the American Medical Association—is key to PromarkerD reimbursement being covered by both Medicare and private health insurers in the US, and hugely important for enabling affordable access and broad adoption of the test.

The new code for PromarkerD (0385U) was granted to Sonic Reference Laboratory as the clinical laboratory and Proteomics International as the manufacturer, and became effective from 1st April 2023, which means service providers (laboratories) may now begin to report the PromarkerD test using the code.

A critical part of the rollout of PromarkerD is engagement with payers which is ongoing, with the Centers for Medicare & Medicaid Services (CMS) recently listing the code in its CY24 Clinical Laboratory Fee Schedule (CLFS) Annual Laboratory Meeting Code List. This is an essential step towards establishing a payment rate for PromarkerD.

In the United States, an estimated 32 million people, or 11 per cent of the population, live with diabetes.

### **US licensing negotiation in closing stages**

[ASX: 1 March] Proteomics International is finalising the detailed terms of its Exclusive Licence Agreement with Sonic Healthcare USA for use of the Company's PromarkerD predictive test for diabetic kidney disease in the United States. Proteomics International Managing Director Dr Richard Lipscombe said the relationship between the two organisations continues to strengthen, with both working actively towards a successful rollout of PromarkerD across the USA.

The parties signed a binding and exclusive letter of intent in August to enter into an Exclusive Licence Agreement for the PromarkerD test [ASX: 9 August 2022]. A number of key milestones have been achieved under the LOI, including optimisation of the test for a high-throughput environment. PromarkerD became a featured test on the Sonic Reference Laboratory (USA) test menu in October 2022, and a CPT PLA reimbursement code approved in January 2023 (see above). The Company will update the market once the Exclusive Licence Agreement has been signed.

### **Clinical Advisory Board expanded to support PromarkerD USA and global rollout**

[ASX: 26 April] Proteomics International has appointed additional key opinion leaders (KOLs) to its world class PromarkerD Clinical Advisory Board. The new board members comprise highly respected healthcare professionals specialising in primary care diabetes education and management in the United States. These KOLs will be able to provide tailored advice from the 'voice of the customer' (patients and clinicians) perspective on the rollout of PromarkerD.

### **Distribution agreement for PromarkerD in Britain extended**

[ASX: 15 February] Proteomics International extended its distribution agreement with medical diagnostics company Apacor Limited to bring PromarkerD to patients in the United Kingdom. Proteomics International began working with Apacor in 2021 [ASX: 23 November 2021]. Since then, several key milestones have been achieved, including PromarkerD being registered with the UK Medicines & Healthcare products Regulatory Agency, and the publication of National Institute for Health and Care Excellence (NICE) advice on PromarkerD [ASX: 14 December 2022].

Based on this success, Proteomics International and Apacor wished to extend the relationship and agreed to an additional five-year term. Both parties are now working towards the inclusion of PromarkerD in the NICE Guidelines and engaging with the NHS Supply Chain Tender process as part of the commercial rollout of the test in the UK. The updated distribution agreement provides Apacor

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Limited with the exclusive right to sell the immunoassay version of the PromarkerD test in England, Scotland and Wales until 31 January 2028.

### **Application for PromarkerD listing on Australian Medicare Benefits Schedule to be resubmitted**

[ASX: 15 March] The Company's initial application to have PromarkerD listed on the Australian Medicare Benefits Schedule (MBS) was denied, which is common for the majority of first-time submissions to the MBS and Pharmaceutical Benefit Scheme (PBS). The Medical Services Advisory Committee (MSAC) which reviews applications noted the potential wide uptake of the test and long term savings to the Australian health system, whilst also seeking further evidence on how use of the test would change clinical practice. The MSAC decision comes after key bodies in the Company's target markets of the USA and UK moved towards endorsing the test. Proteomics International is confident it can provide the necessary information to address the committee's concerns and intends to resubmit its application.

MSAC's decision on reimbursement is not linked to the separate application for regulatory approval of the PromarkerD immunoassay kit by the Australian Therapeutic Goods Administration (TGA) which is still ongoing [ASX: 2 June 2022].

Further information about PromarkerD is available through the web portal ([www.PromarkerD.com](http://www.PromarkerD.com)).

To visit the PromarkerD virtual product display please see: [www.PromarkerD.com/product](http://www.PromarkerD.com/product)

### **ii) R&D for new diagnostic tests using the Promarker™ pipeline and iii) Analytical services**

During the quarter, Proteomics International continued to advance several of its diagnostic research and development projects using the Company's Promarker™ technology platform. Proteomics International believes its Promarker™ platform has broad applicability and the potential to produce multiple new diagnostic tests to address significant unmet medical needs.

#### **Novel blood test for endometriosis presented at international conference**

[ASX: 24 March] Proteomics International announced the latest results for its potential new world-first blood test for diagnosing endometriosis. The results indicate strong diagnostic performance of the test and were presented at the 70th Annual Meeting of the International Society for Reproductive Investigation (SRI), in Brisbane, 21-25 March 2023.

Endometriosis is a painful disease that affects one in nine women and girls, often starting in teenagers. Proteomics International's simple test uses biomarkers—protein 'fingerprints' in the blood—to screen for the painful condition.

Results presented at the conference show the test can identify endometriosis, with the Company's preferred prototype correctly identifying up to 90 per cent of patients when comparing moderate or severe endometriosis to symptomatic controls (no endometriosis) in a 901 person study. The results also suggest the current gold standard for diagnosis—an invasive surgical procedure—may be misdiagnosing some patients, particularly in the early stages of endometriosis.

Current activities are: 1) to confirm the clinical performance and clinical utility of the test in independent patient cohorts; and 2) to accelerate pathways to commercialisation of the biomarker panel as a new diagnostic screening test for endometriosis. Proteomics International believes a validated test will garner significant interest, both commercially and in the clinic.

### **FORTHCOMING EVENTS**

During the next quarter Proteomics International plans to attend the following conferences:

1. The World Congress on Endometriosis Conference; 3-6 May, Edinburgh, Scotland
2. The Biotechnology Industry Organization (BIO) International Convention; 5-8 June, Boston, Massachusetts, USA
3. The Endocrine Society 2023 Annual Meeting; 15-18 June, Chicago, Illinois, USA

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4. The American Diabetes Association (ADA) Scientific Sessions 2023; 23-26 June, San Diego, California, USA

## FINANCIAL AND CORPORATE HIGHLIGHTS

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Proteomics International's business model is to continue the commercialisation of PromarkerD whilst using its Promarker™ technology platform to create a pipeline of novel diagnostic tests, and offset the cash burn from R&D and product development through its analytical services revenue, coupled with the R&D tax incentive rebate. This diversified model has shown its strength in the current economic climate and enables the group to make optimum use of its resources.

### Revenue & Expenditure

Proteomics International achieved cash receipts from customers for the March quarter of \$187,000 (December \$1.1 million). The net operating cash outflow for the March quarter was \$1.7 million (December quarter inflow \$597,000). Expenditure centred on the following areas:

- Business development and commercialisation costs for the rollout of PromarkerD
- Manufacturing costs for the PromarkerD immunoassay kit
- Regulatory and reimbursement activities to support PromarkerD commercialisation
- R&D for projects in the Promarker™ diagnostics pipeline

### Exercise of options

[ASX: 11, 19, 27 January; 7, 14 February; 17, 27 March] Additional funds were received following the exercise of options raising \$3.1 million before costs.

### ASX Listing Rule 4.7C

Payments at item 6.1 of Appendix 4C of \$146,000 relate to normal remuneration of Executive and Non-Executive Directors.

### Cash position

At 31 March 2023 the Company had cash reserves of \$8.08 million (December \$6.8 million).

Authorised by the Board Proteomics International Laboratories Ltd (ASX.PIQ).

ENDS

### About Proteomics International Laboratories (PILL) ([www.proteomicsinternational.com](http://www.proteomicsinternational.com))

Proteomics International (Perth, Western Australia) is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company at the forefront of predictive diagnostics and bio-analytical services. The Company specialises in the area of proteomics – the industrial scale study of the structure and function of proteins. Proteomics International's mission is to improve the quality of lives by the creation and application of innovative tools that enable the improved treatment of disease.

### For further information please contact:

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## Appendix 4C

### Quarterly report for entities subject to Listing Rule 4.7B

**Name of entity**

<b>Proteomics International Laboratories Ltd</b>	
<b>ABN</b>	<b>Quarter ending ("current quarter")</b>
<b>78 169 979 971</b>	<b>31 March 2023</b>

<b>Consolidated statement of cash flows</b>	<b>Current Quarter \$A'000</b>	<b>Year to date \$A'000</b>
<b>1. Cash flows related to operating activities</b>		
1.1 Receipts from Customers	187	1,550
1.2 Payments for		
(a) research & development	(958)	(3,349)
(b) product manufacturing & operating costs	(111)	(518)
(c) advertising & marketing	(77)	(161)
(d) leased assets	0	0
(e) staff costs	(557)	(1,977)
(f) administration & corporate costs	(227)	(995)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	45	53
1.5 Interest & other costs of finance paid	0	0
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	0	1,865
1.8 Other (provide details if material)	0	0
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,698)</b>	<b>(3,532)</b>
<b>2. Cash flows related to investing activities</b>		
2.1 Payments to acquire:		
(a) entities	0	0
(b) businesses (see item 10)	0	0
(c) property, plant & equipment	(146)	(1,214)
(d) investments	0	0
(e) intellectual property	0	0
(f) other non-current assets	0	0
2.2 Proceeds from disposal of:		
(a) entities	0	0
(b) businesses (see item 10)	0	0
(c) property, plant & equipment	0	0
(d) investments	0	0
(e) intellectual property	0	0
(f) other non-current assets	0	0
2.3 Cash flows from loans to other entities	(12)	(12)
2.4 Dividends received (see note 3)	0	0
2.5 Other (provide details if material)	0	0
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(158)</b>	<b>(1,226)</b>

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<b>Consolidated statement of cash flows</b>	<b>Current Quarter</b>	<b>Year to date</b>
	<b>\$A'000</b>	<b>\$A'000</b>
<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	3,133	11,401
3.2 Proceeds from issue of convertible debt securities	0	0
3.3 Proceeds from exercise of options	0	0
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(20)	(674)
3.5 Proceeds from borrowings	0	0
3.6 Repayment of borrowings	0	0
3.7 Transaction costs related to loans & borrowings	0	0
3.8 Dividends paid	0	0
3.9 Other (provide details if material)	0	0
<b>3.10 Net cash from / (used in) financing activities</b>	<b>3,113</b>	<b>10,727</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash & cash equivalents at beginning of period	6,823	2,111
4.2 Net cash from / (used in) operating activities (see 1.9 above)	(1,698)	(3,532)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(158)	(1,226)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	3,113	10,727
4.5 Effect of movement in exchange rates on cash held	0	0
<b>4.6 Cash &amp; cash equivalents at end of quarter</b>	<b>8,080</b>	<b>8,080</b>
<b>5. Reconciliation of cash &amp; cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts</b>	<b>Current Quarter</b>	<b>Previous Quarter</b>
	<b>\$A'000</b>	<b>\$A'000</b>
5.1 Bank balance	1,868	611
5.2 Cash deposits	6,212	6,212
5.3 Bank overdrafts	0	0
5.4 Other (provide details)	0	0
<b>5.5 Cash &amp; cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>8,080</b>	<b>6,823</b>
<b>6. Payments to related parties of the entity &amp; their associates</b>		<b>Current Quarter</b>
		<b>\$A,000</b>
6.1 Aggregate amount of payments to related parties and their associates included in item 1		146
6.2 Aggregate amount of payments to related parties and their associates included in item 2		12
<p>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments</p> <p>Payments at 6.1 relate to normal remuneration of Non-Executive and Executive Directors</p> <p>Payments at 6.2 relate to payments to OxiDx Pty Ltd of which Proteomics International Laboratories Limited owns 67%</p>		

<b>7. Financing facilities available</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	0	0
7.2 Credit standby arrangements	0	0
7.3 Other (please specify)	0	0
<b>7.4 Total financing facilities</b>	<b>0</b>	<b>0</b>
<b>7.5 Unused financing facilities available at quarter end</b>		<b>0</b>
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well. N/A		
<b>8. Estimated cash outflows for next quarter</b>		
8.1 Net cash from / (used in) operating activities (see 1.9 above)		\$A'000 (1,698)
8.2 Cash and cash equivalents at quarter end (Item 4.6)		8,080
8.3 Unused financing facilities available at quarter end (Item 7.5)		0
8.4 Total available funding (Item 8.2 + Item 8.3)		8,080
<b>8.5 Estimated quarters of funding available at quarter end (Item 8.4 divided by Item 8.1)</b>		<b>4.8</b>
8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:		
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?		
Answer:		
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?		
Answer:		
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?		
Answer:		
Note: where item 8.5 is less than 2 quarters, all of the questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.		

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## Compliance Statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 27 April 2023

Authorised by: The Board

(Name the body or officer authorising release - see note 4)

### Notes

1. The quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entities activities for the past quarter, how they have been financed and the effect this has had on the cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of AASB 107: Statement of Cash Flows apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee-eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.